

PTO/SB/21 (09-04)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/627310-Conf. #1899
	Filing Date	July 25, 2003
	First Named Inventor	Cydney C. BROOKS
	Art Unit	1653
	Examiner Name	R. Mitra
Total Number of Pages in This Submission	Attorney Docket Number	ADY-009

## ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): PTO form SB/08 Copies of Three (3) References Certificate of Mailing Return Receipt Postcard
<b>Remarks</b>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

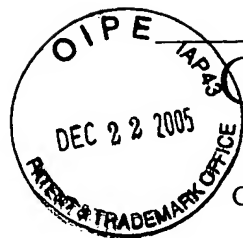
Firm Name	LAHIVE & COCKFIELD, LLP		
Signature			
Printed name	Debra J. Milasincic		
Date	December 20, 2005	Reg. No.	46,931

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Dated: December 20, 2005

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(Debra J. Milasincic)



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\* Admitted in TX only  
\*\* Admitted in CT only

December 20, 2005

Via Federal Express

Mr. Shuichi Takahashi, Senior Manager, Patents  
TAKEDA CHEMICAL INDUSTRIES, LTD.  
Intellectual Property Department  
10, Wadai, Tsukuba  
300-4293 Ibaraki  
JAPAN

Re: U.S. Patent Application No. 10/627,310  
Title: METHODS FOR TREATING DIABETES AND INSULIN RESISTANCE  
Filing Date: July 25, 2003  
Inventor: Cydney C. Brooks  
Your Reference: 3086USON  
Our Reference: ADY-009

Dear Mr. Takahashi:

Enclosed please find an Information Disclosure Statement, PTO form SB/08 and copies of the references cited therein that we recently filed with the U.S. Patent and Trademark Office for the above-referenced patent application.

If you have any questions, please do not hesitate to contact us.

Best regards,

LAHIVE & COCKFIELD, LLP

Debra J. Milasincic, Esq.

DJM/JAM/smn

Enclosures

cc: Gerri Waloga, Ph.D. (w/encl.)  
Jill A. Mello, Ph.D. (w/o encl.)



PTO/SB/17 (12-04v2)

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Effective on 12/08/2004.</b> <b>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</b>		<b>Complete if Known</b>	
<b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		Application Number	10/627310-Conf. #1899
		Filing Date	July 25, 2003
		First Named Inventor	Cydney C. BROOKS
		Examiner Name	R. Mitra
		Art Unit	1653
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Attorney Docket No.	ADY-009
<b>TOTAL AMOUNT OF PAYMENT</b>		<b>(\$)</b>	<b>180.00</b>

<b>METHOD OF PAYMENT</b> (check all that apply)	
<input type="checkbox"/> Check	<input type="checkbox"/> Credit Card
<input type="checkbox"/> Money Order	<input type="checkbox"/> None
<input type="checkbox"/> Other (please identify): _____	
<input checked="" type="checkbox"/> Deposit Account	Deposit Account Number: <u>12-0080</u> Deposit Account Name: <u>Lahive &amp; Cockfield, LLP</u>
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

<b>FEE CALCULATION</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
	<b>FILING FEES</b>		<b>SEARCH FEES</b>		<b>EXAMINATION FEES</b>		
		<b>Small Entity</b>		<b>Small Entity</b>		<b>Small Entity</b>	
<b>Application Type</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fees Paid (\$)</b>
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
<b>2. EXCESS CLAIM FEES</b>							
<b>Fee Description</b>	<b>Fee (\$)</b>	<b>Small Entity Fee (\$)</b>					
Each claim over 20 (including Reissues)	50	25					
Each independent claim over 3 (including Reissues)	200	100					
Multiple dependent claims	360	180					
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Multiple Dependent Claims</b>			
_____	_____	_____	_____	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>				
_____	_____	_____	_____				
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>			
_____	_____	_____	_____	_____			
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)							
Other (e.g., late filing surcharge): <u>806 Submission of an Information Disclosure Statement</u>				<b>Fees Paid (\$)</b>			
				<u>180.00</u>			

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	46,931
Name (Print/Type)	Debra J. Milasincic	Telephone	(617) 227-7400
		Date	December 20, 2005

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Dated: December 20, 2005

Signature:

(Debra J. Milasincic)



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December 19, 2005

Via Federal Express

Mr. Shuichi Takahashi, Senior Manager, Patents  
TAKEDA CHEMICAL INDUSTRIES, LTD.  
Intellectual Property Department  
10, Wadai, Tsukuba  
300-4293 Ibaraki  
JAPAN

Re: U.S. Patent Application No. 10/627,310  
Title: METHODS FOR TREATING DIABETES AND INSULIN RESISTANCE  
Filing Date: July 25, 2003  
Inventor: Cydney C. Brooks  
Your Reference: 3086USON  
Our Reference: ADY-009

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Dear Mr. Takahashi:

Enclosed please find an Office Action mailed from the U.S. Patent and Trademark Office on November 4, 2005 relating to the above-identified application. A Response to this Office Action is due on or before **February 4, 2006**, although this period can be extended monthly until **May 4, 2006** upon payment of an extension fee.

Briefly summarizing the Office Action, our traversal of the Examiner's Restriction Requirement, as set forth in the Response to Restriction Requirement filed September 19, 2005, was successful. The Examiner has therefore withdrawn restriction between Groups IX and X, such that claims 9-12 are currently under examination. The Examiner rejects claims 9-12 for indefiniteness and further rejects claims 9-12 as being anticipated by Tojo *et al.* (US 2004/0072742 A1). A copy of Tojo *et al.*, as well as another reference cited in the Office Action (Westendorf *et al.*), is enclosed.

Accordingly, unless instructed otherwise, we will proceed with preparing an Amendment and Response to the Office Action in which we will also add new claims directed to the elected subject matter.

Mr. Shuichi Takahashi  
December 19, 2005  
Page 2

In the meantime, if you have any questions or comments, please do not hesitate to contact us.

Best regards,

LAHIVE & COCKFIELD, LLP



Debra J. Milasincic, Esq.

DJM/JAM/smn

Enclosures

cc: Gerri Waloga, Ph.D. (w/encl.)  
Jill A. Mello, Ph.D. (w/o encl.)



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Dated: December 20, 2005 Signature: (Debra J. Milasind)

Docket No.: ADY-009  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Cydney C. Brooks

Application No.: 10/627310

Confirmation No.: 1899

Filed: July 25, 2003

Art Unit: 1653

For: METHODS FOR TREATING DIABETES  
AND INSULIN RESISTANCE

Examiner: R. Mitra

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 12-0080 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. ADY-009. A duplicate copy of this paper is enclosed.

Dated: December 20, 2005

DJM/JAM/mch

Respectfully submitted,

By

Debra J. Milasincic

Registration No.: 46,931

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Boston, Massachusetts 02109

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Attorney/Agent For Applicant



PTO/SB/08a/b (07-05)

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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/627310-Conf. #1899
				Filing Date	July 25, 2003
				First Named Inventor	Cydney C. BROOKS
				Art Unit	1653
				Examiner Name	R. Mitra
Sheet	1	of	1	Attorney Docket Number	ADY-009

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Tominaga, Tomoko, et al., "Diaphanous-Related Formins Bridge Rho GTPase and Src Tyrosine Kinase Signaling," <i>Molecular Cell</i> , Vol. 5:13-25 (2000)	
	C2	Westendorf, Jennifer J., "The Formin/Diaphanous-related Protein, FHOS, Interacts with Rac1 and Activates Transcription from the Serum Response Element," <i>The Journal of Biological Chemistry</i> , Vol. 276(49):46453-46459 (2001)	
	C3	Westendorf, Jennifer J., et al., "Identification and characterization of a protein containing formin homology (FH1/FH2) domains," <i>Gene</i> , Vol. 232:173-182 (1999)	

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Application No. (if known): 10/627310

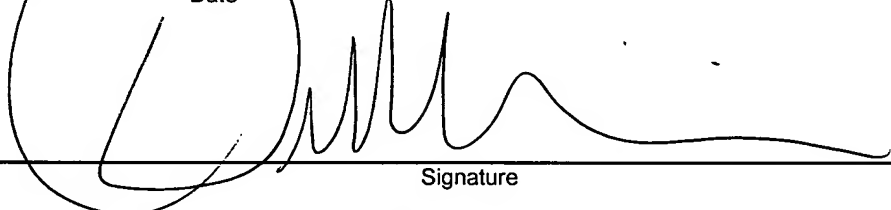
Attorney Docket No.: ADY-009

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on December 20, 2005  
Date

  
Signature

Debra J. Milasincic

Typed or printed name of person signing Certificate

46,931

Registration Number, if applicable

(617) 227-7400

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

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PTO form SB/08 (3 References) (1 page)  
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